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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,264	03/12/2004	Don Fishbein	52427-AA/JPW/GJG	8229

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John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

LEWIS, AMY A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,264

Applicant(s)

FISHBEIN, DON

Examiner

Amy A. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/25/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Case

The Amendments and Remarks, filed 25 November 2005, have been entered into the application. Accordingly, claims 1, 2, and 16 have been cancelled, and claims 30-45 have been added.

Claims 30-45, as filed 25 November 2005, are presented for examination.

Response to Remarks:

1) Claims 1, 2, and 16 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, and 16 of copending Application No. US 2004/0235940 A1. This rejection is rendered *moot* due to cancellation of the claims.

2) Claims 1, 2, and 16 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 6,576,659 B1. This rejection is rendered *moot* due to cancellation of the claims.

3) Claims 1, 2, and 16 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 6,828,313 B2. This rejection is rendered *moot* due to cancellation of the claims.

The following new rejections are necessitated by amendment:

Double Patenting

Obviousness Type Double Patenting:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 30-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-28 of copending Application No. US 2004/0235940 A1.

Instant claims 30-45 are drawn to a method of promoting weight gain after weight loss resulting from post-burn catabolism in a patient which comprises administering a therapeutically effective amount of oxandrolone in conjunction with a protein supplement. Conflicting claims 15-28 of US 2004/0235940 A1 are drawn to the same method of treating burn-induced weight loss in a patient comprising administering oxandrolone in conjunction with a protein supplement. Claims 15-29 of US 2004/0235940 A1 patent specify the same routes of administration and dosages of oxandrolone. Since the same agent (oxandrolone) is being used to treat the same

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conditions (burn induced weight loss), the instant application is an obvious variation of claims 15-29 of US 2004/0235940 A1.

2) Claims 30-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-20 of U.S. Patent No. 6,576,659 B1.

Instant claims 30-45 are drawn to a method of promoting weight gain after weight loss resulting from post-burn catabolism in a patient which comprises administering a therapeutically effective amount of oxandrolone in conjunction with a protein supplement. Conflicting claims 12-20 of U.S. Patent No. 6,576,659 B1 are drawn to the same method of treating burn-induced weight loss in a patient comprising administering oxandrolone in conjunction with a protein supplement. Claims 12-20 of the '659 patent specify the same routes of administration and dosages of oxandrolone. Since the same agent (oxandrolone) is being used to treat the same conditions (burn induced weight loss), the instant application is an obvious variation of claims 12-20 of U.S. Patent No. 6,576,659 B1.

3) Claims 30-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-31 of U.S. Patent No. 6,828,313 B2.

Instant claims 30-45 are drawn to a method of promoting weight gain after weight loss resulting from post-burn catabolism in a patient which comprises administering a therapeutically effective amount of oxandrolone in conjunction with a protein supplement. Conflicting claims 18-31 of U.S. Patent No. 6,828,313 B2 are drawn to the same method of increasing weight gain after burn-induced weight loss in a patient comprising administering oxandrolone in conjunction

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with a protein supplement. Claims 18-31 of the '313 patent specify the same routes of administration and dosages of oxandrolone. Since the same method and agents are being used to treat the same condition, i.e. burn-induced weight loss, the instant application is an obvious variation of claims 18-31 of U.S. Patent No. 6,828,313 B2.

Conclusion

Claims 30-45 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information:

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis
Patent Examiner
Art Unit 1614



Christopher Low
SPE
Art Unit 1614



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600